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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/390,740	02/17/95	COLEMAN R	

HM12/0423

LEGAL DEPARTMENT
INCYTE PHARMACEUTICALS, INC.
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EXAMINER	
MARSCHEL, A	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 04/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/390,740	Coleman et al.
Examiner	**Art Unit**
Ardin Marschel	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 12, 2001*

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *40-60* is/are pending in the applica

4a) Of the above, claim(s) *43-45, 48-51, and 55-60* is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *40-42, 46, 47, and 52-54* is/are rejected.

7) ☒ Claim(s) *1-39 have been canceled.* is/are objected to.

8) ☒ Claims *40-60* are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Newly submitted claims 43-45, 48-51, and 55-60 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The previously elected and examined invention is directed to recombinant DNA molecules comprising panec-1 and 2, expression vectors and host cells containing said nucleic acids, and diagnostic tests using said nucleic acids as summarized for Group I in the restriction requirement, mailed 12/28/95. This Group I was elected by applicants with traverse in a telephone conversation with Barbara J. Luther on Dec. 14, 1995. In applicants next response, filed 5/3/96, non-elected claims were canceled as being drawn to a non-elected invention as stated therein. In the next Office action, mailed 11/15/96, the election was noted as being treated as an election without traverse. It is noted that newly submitted claims include both inventions non-elected as noted above as well as new distinct invention. The previously non-elected inventions are as follows:

Original non-elected Group III drawn to methods of producing PANEC-1 and PANEC-2 polypeptides and panec-1 and panec-2 polypeptides, now claims 43-45, 48-50, and 55-57

Original non-elected Group IV drawn to antibodies, immunoassays, pharmaceutical compositions and methods of treatment, now claim 51

The newly submitted claims also include claims 58-60 drawn

to independent or distinct inventions for the following reasons:

The inventions of Groups I and II and claim 60 (now designated as newly submitted Group VI), and newly submitted claims 58 and 59 (now designated as newly submitted restriction Group V) and previously submitted Groups III, and Group IV are independent inventions because they are directed to different chemical types regarding the critical limitations therein. For Groups III and V the critical feature is a polypeptide whereas for Groups I, II, and VI the critical feature is a polynucleotide also whereas the critical feature for Group IV is an antibody. It is acknowledged that various processing steps may cause a polypeptide of Groups III or V to be directed as to its synthesis by a polynucleotide of Groups I, II, or VI, however, the completely separate chemical types of the inventions of Groups I, II, and VI, versus Groups III and V, versus Group IV supports the undue search burden if both were examined together.

Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being searched separately..

Also, it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to

additions, subtractions, enzyme action, etc.

The inventions of Groups I and II versus new Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the polynucleotides of Group I can be utilized in the materially different uses of either antisense practice as in Group II or screening for methods of Group VI or, also alternatively, in the production of a polypeptide of Group III.

The inventions of Group III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the polypeptides of Group III can be utilized in the distinct processes of diagnostic assays such as immunoassays as already included in Group III or the distinct Group V usage for agonist or antagonist screening which is directed to polypeptide activity which is distinct from basic immunoassay binding assay usage.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 43-45, 48-51, and 55-60 are withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

Applicants' arguments, filed 2/12/01, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because no submission of the nucleotide sequence given in Figure 1 has been received on computer readable form or in the sequence listing in the specification. This Figure 1 nucleotide sequence is 291 nucleotides in length. It is noted that the sequence listing does contain a 289 nucleotide sequence as SEQ ID NO: 1, but is as noted only 289 nucleotides in length. Applicants are also hereby reminded that sequences in

Drawings/Figures must be present in computer readable form etc., if they meet the sequence rule requirements, but that Drawings/Figures are not required to contain the sequence number therein such as "SEQ ID NO:__". Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action. The request to hold this requirement is abeyance is acknowledged, but the need to comply with the sequence rules remains as summarized above.

Claims 40-42, 46, 47, and 52-54 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly submitted limitations in the claims directed to "stringent" hybridization conditions has not been found as filed nor pointed to by applicants. This is a specific set of conditions and is not supported, via written basis, by generic hybridization conditions or hybridizability. These limitations are therefore NEW MATTER. This rejection is necessitated by amendment.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-42, 46, 47, and 52-54 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

Claims 40-42, 46, 47, and 52-54 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

The above two rejections are maintained and reiterated from the previous office action, mailed 9/7/00, and as necessitated by amendment due to newly added claims. The above two rejections are argued together by applicants and are therefore also responded to together as follows. Applicants firstly argue that BLAST2 reports document up to 100% identity with a number of human leukocyte-specific chemoattractants and therefore one skilled in the art could not doubt that PANEC-1 and -2 are

leukocyte-specific chemokines. In response, no BLAST2 reports were found attached as alleged by applicants. Therefore, the sequence identity is an allegation without factual support and thus non-persuasive. Additionally, the phrase "up to 100%" is confusing as to what that means. Does it include 90% identity, 75% identity, 50% identity, or lower? Are any identity matches at 100%? Without the BLAST2 reports the identity argument is impossible to reasonably evaluate.

Applicants then argue that specific utilities have been overlooked or ignored. Applicants then allege that the claimed invention is a leukocyte-specific chemokine. As noted above the chemokine identity is not supported by sequence identity. Additionally, leukocyte specificity is also not supported in that this suggests that PANEC-1 and/or -2 is expressed in leukocytes and not in other cell types. No evidence or even scientific reasoning to support this has been set forth. It is well known that humans grow from cells with all genes therein for that human being which then are present in normally growing cells such as leukocytes, muscle cells, skin cells, liver cells, lung cells, etc. Thus the instant polynucleotides are reasonably expected to be present in every normally growing cell in the human body. What, therefore, supports the speculation that PANEC-1 and/or -2 is leukocyte specific? It is noted that a pancreas library was utilized as described in the instant specification on page 14 to isolate Panec-1 and -2 cDNAs. Nowhere is there an indication

that a muscle, skin, liver, lung, etc. library would or would not be equally usable for the isolation of exactly the same cDNAs. A reasonable expectation is, in fact, that these other libraries would contain these cDNAs because, as noted above, the cells from which such other libraries would be made reasonably contain the genes for every expressed sequence as well as unexpressed sequences. It is acknowledged that there are specific genes that are only expressed in certain cell types, but, until expression is tested so as to define specificity, it is just as likely as not that a particular gene is expressed in every cell type, no cell types, or in some cell types. In summary, the allegations of applicants regarding both that the instantly claimed polynucleotides are leukocyte-specific as well as chemokines are speculations without factual support. The above noted argument directed to overlooked or ignored utilities seem to be based on the characteristics of the invention as being leukocyte-specific and a chemokine. Since these characteristics have no factual support, the list of basic genetic engineering procedures such as attracting leukocytes, gene therapy, etc. lack specific and substantial utility due to lacking reasonably supported characteristics which would guide someone of skill in the art in such procedures. Clearly further research is required before a "currently available" utility is present. as required in Brenner v. Manson. Applicants are advised that the results of such further research which may then support a specific and

substantial utility is commonly supplied in a continuation-in-part type of patent application. Applicants then argue non-specific or non-substantial usages for the instant invention such as generic toxicology testing, drug discovery, and disease diagnosis. For example, expression profiling is cited. It is noted that specific expression of Panec-1 and/or -2 has not been supported. Thus, generic usage of Panec-1 and/or -2 apparently what applicants are relying on in such profiling. It is firstly noted that expression profiling indicates that numerous expressed sequences are analyzed. Thus, utility in such cases requires numerous sequences which is deemed to be many more than only 2 sequences as instantly claimed. Thus, the instant invention per se fails to support expression profiling utility. Applicants further indicate that specific expression or not of a gene is useful in toxicology either as a control versus a variable for study. It is noted that further research would be required as to whether panec-1 and/or -2 is a control or variably expressed sequence. Inventions which achieve utility only after further research do not have currently available utility as required in Brenner v. Manson. Applicants then argue that databases have been commercially useful as indicated in various published articles. The instant invention is directed to two related sequences and may be part of such databases, but the apparent utility of such databases is the broad set of expressed sequences therein and not one portion only such as 2 related sequences

therein. Even if such databases may have a well established utility, it is not seen how 2 related sequences therein, especially if not described as being in such a database, has the utility of such a database. In part B of applicants arguments, the specific utility requirement is argued in that the how or why an invention works is not a requirement. This is acknowledged in that there has not been any basis for these rejections based on any how or why requirements. Applicants then argue that the expression in "humans" is sufficient for utility and that being in a broad class of inventions is sufficient to meet the utility requirement. As noted above the being in humans is not sufficient because it is non-specific as to what use it is applied to without further research. This is again not a "currently available" utility. Applicants then argue analogy to conductive materials, plastics, steriods, and fishing rods. These have well established utilities such as electrical conductors, film making, hormonal effects, and recreation no matter what fish is or is not caught, as agreed with applicants. What such utilities are present for the instant invention? None have been noted. Applicants end this section stating that just as there is no useless interleukins and GPCRs, there are no useless leukocyte-specific chemokines. If applicants supported the leukocyte specificity as well as the chemokine activity function of the instant invention, this may overcome these rejections. Unfortunately, applicants have not supported either

of these characteristics as noted above and therefore this argument is non-persuasive as based on speculation which requires at least further research before arriving at a "currently available" utility. The remainder of applicants arguments regarding these rejections are directed to database utility, alleged utility, etc. that rely on the allegation that Panec-1 and/or -2 are leukocyte-specific and chemokines, neither characteristic of which has been reasonably supported as noted above. The general legal decisions as listed by applicants in support of various aspects of utility regarding throwaway utilities and the acknowledgement of well established utilities is acknowledged and agreed with. These rejections, however, do not follow the fact pattern of any of these decisions as to having utility because of the above noted reasonably doubt as to what panec-1 and/or -2 is specific or not for and what activity it may or may not have. Thus, the instant invention cannot reasonably be drawn into a class of invention with a well established utility because further research is required to reasonably include them is any such class. Therefore, in summary these rejections are maintained and reiterated from the previous office action, mailed 9/7/00, and as necessitated by amendment regarding newly added claims.

Claims 40-42, 46, and 47 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while providing written description enablement SEQ ID NOs: 1 and 3, does not

reasonably provide written description enablement for genomic sequences etc. as summarized below. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

This rejection is maintained and reiterated from the previous office action, mailed 9/7/00, and as necessitated by amendment regarding newly added claims.

The specification discloses SEQ ID NOs: 1 and 3 which correspond to the cDNA encoding the PANEC-1 and PANEC-2 protein species, respectively. It is noted that cDNA cloning resulted in illucidating said SEQ ID NOs: 1 and 3 as given in the instant specification on pages 15-16, but that section V on page 17 lacks disclosure of a full length gene sequence. SEQ ID NOs: 1 and 3 per se meet the written description and enablement provisions of 35 USC 112, first paragraph. However, the above listed claims are directed to encompass full gene sequences, sequences that hybridize to SEQ ID NOs: 1 or 3, corresponding sequences from other species, mutated sequences, allelic variants, splice variants, and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. Applicants argue that the genomic sequence disclosure is totally unnecessary. In response, the claims include a scope which does, in fact, include

such genomic sequences as encoding amino acid sequences and therefore enabling disclosure is necessary to overcome this rejection. The previously stated portion of the basis of this rejection directed to variants has been persuasively argued and is withdrawn as a basis for this rejection, however, the above issue remains. Therefore, only SEQ ID NOs: 1 and 3 and hybridizable sequences thereto but not the full breadth of the claims meet the written description provision of 35 USC 112, first paragraph.

Claims 40-42, 46, 47, and 52-54 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims include sequences which are "complementary" to other sequences. This wording causes the claims to be vague and indefinite as to what the metes and bounds of such complementary practice is. One interpretation is that complementary requires that the intended sequence be fully complementary and of the same length as what it is complementary to. This would exclude additional flanking sequences. Another reasonable interpretation is that complementary nucleic acids hybridize with less than the fully complementary and same length requirements above. Thus, a sequence which is longer or shorter than the target sequence or with less than 100% complementarity may be meant, such as 90%,

60%, or even 10% complementarity or complementary to a subsegment of a longer sequence. It is noted that even a 10% complementary sequence is still "complementary" but may be not what is meant due to lacking in usefulness as a hybridization probe, for example. It is noted that claim 40, for example, does not limit the complementarity to requiring a use such as reasonably a probe that may be able to function in a hybridization assay in a complex human sample to specifically detect a Panec-1 or -2 expression product. Thus, the claims are confusing as to what complementary practice is meant to define the metes and bounds of claims with this wording. Clarification via clearer claim wording is requested. This rejection is necessitated by amendment.

Claim 53 and 54 are additionally vague and indefinite as to what is meant for the metes and bounds of the claim practice. In claim 53, for example, lines 1-2, a method of detecting a target polynucleotide is set forth as the intent of the claim, but confusingly, no step therein actually is stated as indicating such detection. Step b), for example, in claim 53 detects a hybridization complex but lacks any indication as to whether this detection is meant to determine the presence or absence of the target polynucleotide in the sample. It is also noted that a probe is utilized which may be a subsegment of a longer target but it is additionally unclear whether the entire target is present in the sample if only a subsegment is detected. Is there

a step which requires that only sample polynucleotides containing a particular subsegment also contains the full length target as cited in lines 1-2 of claim 53? Such a requirement has not been found in either claims 53 or 54. Clarification via clearer claim wording is requested. This rejection is necessitated by amendment.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40 and 52 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Esposito et al. (JBC, Vol. 263, pp. 11466-11472[1988]).

This rejection is maintained and reiterated from the previous office action, mailed 9/7/00, as necessitated by amendment regarding newly added claims. It is noted that applicants argue that hybridization over the full length is needed. In response this rejection is based on the complementary limitations of instant claims 40 and 52 which do not contain any full length complementarity limitation.

Instant claims 40 include nucleic acid sequences which are complementary to the nucleic acids of SEQ ID NOs: 1 and 3,

respectively. Significant complementarity is shown below for two sequences from the reference which are capable of hybridization to each of the instantly cited sequences as follows:

```
reference seq 5(Table I, page 11468)  3'-GGGGGCCCCC-5'
                                        ||||| ||||
            instant SEQ ID NO: 1:  5'...CCCCCAGGGG...3'
                                      (bases 54-63)
```

complementarity at 9 of 10 bases = 90%

or

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reference seq 1(Table I, page 11468)  3'-CCCCCGGGGG-5'
                                        ||||||| ||
            instant SEQ ID NO: 3:  5'...GGGGGCCTCC...3'
                                      (bases 321-330)
```

complementarity of 9 of 10 bases - 90%

The disclosure is objected to because of the following informalities:

It is noted that six Figures are present in the instant application file whereas confusingly there is no brief description of Figure 6 on page 6 of the specification. Rather there are two Figure 5 descriptions.

Appropriate correction is required.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to chemokines which are proteins whereas in contrast the elected invention is directed to polynucleotides encoding said chemokines. Additionally, the instant invention is directed to

PANEC-1 and PANEC-2 leukocyte-specific chemokines and not generic chemokines as presently worded in the present title.

Enclosed is a PTO-948 form which apparently was inadvertently not previously mailed.

No claim is allowed.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

This application contains claims 43-45, 48-51, and 55-60; drawn to an invention non-elected without traverse in Paper Nos. 5 and 7; applicants' response Paper No. 7, filed 5/3/96. A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action (37 C.F.R. § 1.144) M.P.E.P. § 821.01.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center

number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

April 20, 2001

ARDIN H. MARSCHEL
PRIMARY EXAMINER